State and Federal Pharmacy Law Applicable to Walk-In IV Therapy Clinics

Board staff have fielded a number of inquiries from licensed medical professionals concerning clinics that offer walk-in intravenous therapy services. This statement sets forth North Carolina law governing the need for pharmacy permits and the preparation of sterile drug products.

North Carolina law (G.S. 90-85.3 (q)) defines a pharmacy as "any place where prescription drugs are dispensed or compounded."

North Carolina law (G.S. 90-85.3(c)) defines compounding as "taking two or more ingredients and combining them into a dosage form of a drug, exclusive of compounding by a drug manufacturer, distributor, or packager." Likewise, the federal Food and Drug Administration (FDA) defines compounding as "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs." See https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers

Compounding does not include mixing, reconstituting, or other such acts if – and only if – those acts are performed in accordance with directions expressly included in the drug product's FDA-approved labeling provided by the manufacturer. The product labeling must include instructions about the diluent, the resulting strength, the container closure system, and storage time.

Accordingly, a place that compounds intravenous drug products is a "pharmacy" and must be properly permitted as such.

Furthermore, compounding any drug product requires adherence to applicable quality and safety standards – in particular, relevant United States Pharmacopeia ("USP") chapters. This is required by state law (21 NCAC 46.2801) and by federal law (21 USC § 353a).

USP, which – like North Carolina and federal law – defines compounding as combing, mixing, pooling, diluting, and reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk drug substance to create a sterile or non-sterile medication, sets standards for compounding practices to ensure that compounded drug products are prepared and handled safely. North Carolina and federal law incorporate USP Chapters <797> and <795>, including all USP chapters incorporated into Chapters <797> and <795> by reference, and all subsequent amendments and editions. USP Chapters <797> and <795> govern both sterile and non-sterile compounded products, respectively. These Chapters also govern the physical and environmental conditions under which sterile and non-sterile compounded products are prepared, labeled, and dispensed.

The North Carolina Board of Nursing (NCBON) has also created a guidance document for licensed nurses and nurse practitioners affiliated with clinics offering walk-in services involving intravenous therapies. That document can be found here:

https://www.ncbon.com/myfiles/downloads/position-statements-decision-trees/iv-hydration-clinics.pdf

FAQs

Q. Would compounding sterile drug products for walk-in intravenous therapy be considered "Immediate Use" if it is administered within an hour of preparation?

A. No. USP Chapter <797>'s "immediate use" provision governs the emergency preparation of a sterile drug product, and in certain circumstances, this provision allows for the preparation of a sterile product to be made outside of full USP <797> compliance. The provision is intended only for those situations where there is a need for emergency or immediate patient administration of a compounded sterile product (CSP). Such situations may include cardiopulmonary resuscitation, emergency room treatment, or critical therapy where the preparation of the CSP under conditions described USP <797> subjects patients to additional risk due to delay in therapy. This provision is not a workaround for the quality and safety standards that govern sterile product preparation. Walk-in intravenous therapy services do not fall into this provision.

Q. What is an example of preparing per FDA approved labeling?

A. An example would be mixing Rocephin with lidocaine for IM use in the ED. Rocephin package insert:

Method of administration

As a general rule the solutions should be used immediately after preparation.

Reconstituted solutions retain their physical and chemical stability for 6 hours at room temperature (or 24 hours in the refrigerator at 2 – 8 °C). The solutions range in colour from pale yellow to amber, depending on the concentration and length of storage. The coloration of the solutions is of no significance for the efficacy or tolerance of the drug.

Intramuscular injection

For i.m. injection, Rocephin 250 mg or 500 mg is dissolved in 2 ml, and Rocephin 1 g in 3.5 ml, of 1% lidocaine hydrochloride solution and injected well within the body of a relatively large muscle. It is recommended that not more than 1 g be injected at one site. The lidocaine solution should never be administered intravenously *(see section 2.3 Contraindications)*.

Q. How do you apply for a North Carolina Board of Pharmacy permit?

A. You can begin the application process for a pharmacy permit by following the instructions found at this link:

http://www.ncbop.org/Forms%20and%20Applications%20-%20Pharmacies/InStatePharmacyApplicationInstructions.pdf

Q. What is an "outsourcing facility," and how can I verify that any sterile compounded products I purchase from an outsourcing facility are from a place licensed in North Carolina?

A. The federal Drug Quality and Security Act, signed into law on November 27, 2013, created section 503B of the Federal Food, Drug, and Cosmetic Act. Section 503B defines an outsourcing facility as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all the requirements of section 503B.

Drugs compounded by an outsourcing facility can qualify for exemptions from FDA approval requirements and the requirement to label products with adequate directions for use, but not from current good manufacturing practice (CGMP) requirements.

Outsourcing facilities:

- must comply with CGMP requirements;
- are inspected by FDA according to a risk-based schedule; and
- must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

A qualifying outsourcing facility may compound sterile drug product without having received a patient-specific prescription.

Outsourcing Facilities are licensed by the North Carolina Department of Agriculture and Consumer Services. You can verify the status of a licensed Outsourcing facility here:

https://apps.ncagr.gov/agrsysportal/publiclicensesearch/index?owner=FDPD

You can also review the Outsourcing Facilities FDA registration here:

https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities

Q. How should any sterile compounded product I acquire from an outsourcing facility be labeled?

A. The federal Drug Quality and Security Act provides:

21 USC 353b (a) (10) Labeling of drugs

(A) Label

The label of the drug includes-

(i) the statement "This is a compounded drug." or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

(ii) the name, address, and phone number of the applicable outsourcing facility; and

(iii) with respect to the drug-

(I) the lot or batch number;

(II) the established name of the drug;

(III) the dosage form and strength;

(IV) the statement of quantity or volume, as appropriate;

(V) the date that the drug was compounded;

(VI) the expiration date;

(VII) storage and handling instructions;

(VIII) the National Drug Code number, if available;

(IX) the statement "Not for resale", and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only"; and

(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

(B) Container

The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include-

(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

(ii) the following information to facilitate adverse event reporting: **.**

https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program or 1–800–FDA–1088 (or any successor Internet Web site or phone number);

(iii) directions for use, including, as appropriate, dosage and administration.

(C) Additional information

The label and labeling of the drug shall include any other information as determined necessary

and specified in regulations promulgated by the Secretary.